Loly Tor (loly.tor@klgates.com)
K&L GATES LLP
One Newark Center, 10th Floor
Newark, NJ 07102
(T) 973.848.4026
(F) 973.848.4001

Harold Storey
(harold.storey@klgates.com)
(*pro hac vice* application forthcoming)
Elizabeth Weiskopf
(elizabeth.weiskopf@klgates.com)
(*pro hac vice* application forthcoming)
K&L GATES LLP
925 Fourth Avenue, Suite 2900
Seattle, WA 98104
(T) 206.623.7580
(F) 206.623.7022

Anil H. Patel (anil.patel@klgates.com)
(*pro hac vice* application forthcoming)
K&L GATES LLP
609 Main Street, Suite 4150
Houston, TX 77002
(T) 713.815.7300
(F) 713.815.7301

Attorneys for Defendants/Counterclaim-Plaintiffs Cipla USA, Inc. and Cipla Limited

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC. and NORTON (WATERFORD) LTD., Plaintiffs, v. CIPLA USA, INC. and CIPLA LTD., Defendants.	Civil Action No. 2:24-cv-07162 Hon. Stanley R. Chesler, U.S.D.J. Hon. Michael A. Hammer, U.S.M.J. **ANSWER, SEPARATE DEFENSES, AND COUNTERCLAIMS** ***Document Electronically Filed***

Defendants Cipla USA, Inc. and Cipla Limited (collectively, "Cipla" or "Defendants"), by and through their attorneys, respond to each of the numbered paragraphs in the Complaint by

Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc. ("Teva") and Norton (Waterford) Ltd. ("Norton") (collectively, "Plaintiffs") as follows[1]:

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 et seq., which arises out of the submission by Cipla Ltd. and Cipla USA, Inc. (collectively, "Cipla") of Abbreviated New Drug Application ("ANDA") No. 219000 to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import generic versions of Plaintiffs' QVAR RediHaler® (beclomethasone dipropionate, 40 mcg) product prior to the expiration of U.S. Patent No. 11,957,832 (the "'832 patent").

ANSWER: Cipla admits that Plaintiffs' Complaint purports to be based upon the patent laws of the United States, 35 U.S.C. § 100 *et seq*. Cipla admits that Cipla Limited prepared and submitted Cipla's Abbreviated New Drug Application ("ANDA") No. 219000 ("Cipla's ANDA") to the FDA pursuant to 21 U.S.C. § 355(j), and that Cipla's ANDA seeks approval from the FDA to engage in the commercial manufacture, use, and/or sale, of the product described in Cipla's ANDA ("Cipla's ANDA Product") prior to the expiration of U.S. Patent No. 11,957,832 (the "'832 patent").

PARTIES

Teva

2. Plaintiff Teva is a company organized under the laws of the State of Delaware with its principal place of business at 145 Brandywine Parkway, West Chester, Pennsylvania 19380. In addition, Teva has a place of business at 400 Interpace Parkway #3, Parsippany, New Jersey 07054.

ANSWER: Cipla lacks sufficient information or knowledge to admit or deny the allegations in this paragraph and therefore denies them.

3. Plaintiff Norton is a private limited company organized under the laws of the Republic of Ireland and having its registered office at Unit 301, IDA Industrial Park, Waterford

[1] This Answer reproduces the headings of the Complaint for convenience only. This reproduction of the headings should not be construed as an admission of any of the allegations in the Complaint. Pursuant to Federal Rule of Civil Procedure 8(b)(3), Defendants deny all allegations in the Complaint except those specifically admitted.

X91 WK68, Republic of Ireland. Norton trades, i.e., does business, as Ivax Pharmaceuticals Ireland and as Teva Pharmaceuticals Ireland.

ANSWER: Cipla lacks sufficient information or knowledge to admit or deny the allegations in this paragraph and therefore denies them.

Cipla

4. On information and belief, Defendant Cipla Ltd. is a company organized and existing under the laws of the Republic of India with its principal place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai 400 013, Maharashtra, India. On information and belief, Cipla Ltd. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs.

ANSWER: Cipla admits that Cipla Limited is a company organized and existing under the laws of India, having a place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai 400013, India. Cipla admits that Cipla Limited manufactures pharmaceutical drug products, including generic drug products. Cipla denies the remaining allegations in paragraph 4.

5. On information and belief, Defendant Cipla USA, Inc. is a company organized and existing under the laws of the State of Delaware, with its principal place of business at 10 Independence Boulevard, Suite 300, Warren, New Jersey 07059. On information and belief, Cipla USA, Inc. is a wholly owned subsidiary of Cipla Ltd., and is controlled and dominated by Cipla Ltd. On information and belief, Cipla USA, Inc. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs.

ANSWER: Cipla admits that Cipla USA, Inc. is a company organized and existing under the laws of the State of Delaware, with its principal place of business at 10 Independence Boulevard, Suite 300, Warren, New Jersey 07059. Cipla USA, Inc. is a wholly-owned subsidiary of InvaGen Pharmaceuticals, Inc., which is a wholly-owned subsidiary of Cipla (EU Limited), which is a wholly-owned subsidiary of Cipla Limited. Cipla admits that Cipla USA, Inc. distributes pharmaceutical drug products, including generic drug products, for sale. Cipla denies the remaining allegations in paragraph 5.

6. On information and belief, Cipla Ltd., acting in concert with Cipla USA, Inc., files ANDAs with the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of drug products that are covered by United States patents. On information and belief, as part of these ANDAs, Cipla Ltd., acting in concert with Cipla USA, Inc., files certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("Paragraph IV Certifications") to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic drug products prior to the expiration of United States patents that cover such products.

ANSWER: Cipla admits that Cipla Limited seeks regulatory approval of pharmaceutical drug products, including generic drug products. Cipla denies the remaining allegations in paragraph 6.

7. On information and belief, Cipla knows and intends that upon approval of Cipla's ANDA, Cipla will manufacture and directly or indirectly market, sell, and distribute Cipla's Beclomethasone Dipropionate Inhalation Aerosol, 40 mcg ("Cipla's ANDA Product") throughout the United States, including in New Jersey.

ANSWER: Cipla admits that Cipla Limited prepared and submitted Cipla's ANDA to the FDA pursuant to 21 U.S.C. § 355(j), and that Cipla's ANDA seeks approval from the FDA to engage in the commercial manufacture, use, and/or sale of Cipla's ANDA Product. Cipla denies the remaining allegations in paragraph 7.

8. On information and belief, Cipla Ltd. and Cipla USA, Inc. are agents of each other, and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length, including with respect to the development, regulatory approval, marketing, sale, offer for sale, and distribution of generic pharmaceutical products throughout the United States, including into New Jersey, and including with respect to Cipla's ANDA Product at issue.

ANSWER: Paragraph 8 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Cipla denies any and all remaining allegations in paragraph 8.

9. On information and belief, following any FDA approval of Cipla's ANDA, Cipla Ltd. and Cipla USA, Inc. will act in concert to market, distribute, offer for sale, and sell Cipla's ANDA Product throughout the United States and within New Jersey.

ANSWER: Cipla denies the allegations of paragraph 9 as phrased and affirmatively states that Cipla will decide whether to market its product in the United States upon FDA approval.

10. On information and belief, following any FDA approval of Cipla's ANDA, Cipla will market, distribute, offer for sale, and sell Cipla's ANDA Product throughout the United States and within New Jersey.

ANSWER: Cipla denies the allegations of paragraph 10 as phrased and affirmatively states that Cipla will decide whether to market its product in the United States upon FDA approval.

11. On information and belief, following any FDA approval of Cipla's ANDA, Cipla knows and intends that Cipla's ANDA Product will be marketed, used, distributed, offered for sale, and sold in the United States and within New Jersey.

ANSWER: Cipla denies the allegations of paragraph 11 as phrased and affirmatively states that Cipla will decide whether to market its product in the United States upon FDA approval.

JURISDICTION

12. Plaintiffs incorporate each of the preceding paragraphs 1–11 as if fully set forth herein.

ANSWER: In response to paragraph 12, Cipla repeats and realleges its responses to the allegations of paragraphs 1–11 of the Complaint as if fully set forth herein.

13. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a); 28 U.S.C. §§ 2201 and 2202.

ANSWER: Paragraph 13 contains legal conclusions and allegations to which no answer is required. For the limited purpose of this action only, Cipla does not contest subject matter jurisdiction.

14. Based on the facts and causes alleged herein, and for additional reasons to be further developed through discovery if necessary, this Court has personal jurisdiction over Cipla Ltd. and Cipla USA, Inc.

ANSWER: Paragraph 14 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla does not contest personal jurisdiction

over Cipla Limited and Cipla USA, Inc. in this Court for the limited purpose of this litigation, and denies the remaining allegations of paragraph 14.

15. This Court has personal jurisdiction over Cipla USA, Inc. because, among other things, Cipla USA, Inc. has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. Cipla USA, Inc. is a company with a principal place of business in New Jersey. On information and belief, Cipla USA, Inc. develops, manufactures, imports, markets, offers to sell, sells, and/or imports generic drugs throughout the United States, including in New Jersey, and therefore transacts business within New Jersey, and/or has engaged in systematic and continuous business contacts within New Jersey. It therefore has consented to general jurisdiction in New Jersey.

ANSWER: Paragraph 15 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla admits that Cipla USA, Inc. is a corporation organized and existing under the laws of Delaware, with its principal place of business at 10 Independence Boulevard, Suite 300, Warren, New Jersey 07059. Cipla admits that Cipla USA, Inc. markets, sells, and/or distributes pharmaceutical drug products, including generic drug products. Cipla does not contest personal jurisdiction over Cipla USA, Inc. in this Court for the limited purpose of this litigation, and denies the remaining allegations of paragraph 15.

16. On information and belief, Cipla USA, Inc. is responsible for marketing, distributing, offering for sale, and/or selling generic copies of branded pharmaceutical products for the U.S. market, including in New Jersey, and relies on contributions from Cipla Ltd.

ANSWER: Cipla admits that Cipla USA, Inc. markets, sells, and/or distributes pharmaceutical drug products, including generic drug products. Cipla denies the remaining allegations of paragraph 16.

17. On information and belief, Cipla USA, Inc., acting as the agent of Cipla Ltd., markets, distributes, offers for sale, and/or sells in New Jersey and elsewhere in the United States generic pharmaceutical products that are manufactured by Cipla Ltd. or for which Cipla is the named applicant on approved ANDAs.

ANSWER: Paragraph 17 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla admits that Cipla USA, Inc. markets,

sells, and/or distributes pharmaceutical drug products, including generic pharmaceutical drug products. Cipla admits that Cipla Limited manufactures and/or seeks regulatory approval of pharmaceutical drug products, including generic pharmaceutical drug products. Cipla denies the remaining allegations of paragraph 17.

18. This Court has personal jurisdiction over Cipla Ltd. because, among other things, Cipla Ltd. has purposefully availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Cipla Ltd. develops, manufactures, imports, markets, offers to sell, sells, and/or imports generic drugs throughout the United States, including in New Jersey, and therefore transacts business within New Jersey, and/or has engaged in systematic and continuous business contacts within New Jersey.

ANSWER: Paragraph 18 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla does not contest personal jurisdiction over Cipla Limited in this Court for the limited purposes of this litigation. Cipla admits that Cipla Limited is in the business of manufacturing pharmaceutical drug products, including generic pharmaceuticals. Cipla denies the remaining allegations of paragraph 18.

19. In addition, this Court has personal jurisdiction over Cipla USA, Inc. and Cipla Ltd. because, among other things, on information and belief: (1) Cipla USA, Inc. and Cipla Ltd. acted in concert to file Cipla's ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product in the United States, including in New Jersey; and (2) Cipla USA, Inc. and Cipla Ltd., acting in concert and/or as agents of one another, will market, distribute, offer for sale, sell, and/or import Cipla's ANDA Product in the United States, including in New Jersey, upon approval of Cipla's ANDA, and will derive substantial revenue from the use or consumption of Cipla's ANDA Product in New Jersey. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 763 (Fed. Cir. 2016). On information and belief, upon approval of Cipla's ANDA, Cipla's ANDA Product will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in New Jersey; prescribed by physicians practicing in New Jersey; dispensed by pharmacies located within New Jersey; and/or used by patients in New Jersey, all of which would have a substantial effect on New Jersey.

ANSWER: Paragraph 19 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla does not contest personal jurisdiction over Cipla Limited and Cipla USA, Inc. in this Court for the limited purpose of this litigation.

Cipla admits that Cipla Limited prepared and submitted Cipla's ANDA to the FDA pursuant to 21 U.S.C. § 355(j). Cipla admits that Cipla's ANDA seeks approval from the FDA to engage in the commercial manufacture, use, and/or sale of the product described in Cipla's ANDA. Cipla will decide whether to market, distribute, offer for sale, sell, and/or import its product in the United States upon FDA approval. Cipla denies the remaining allegations of paragraph 19.

20. In addition, this Court has personal jurisdiction over Cipla USA, Inc. and Cipla Ltd. because Cipla USA, Inc. and Cipla Ltd. regularly (1) engage in patent litigation concerning FDA approved branded drug products in this District, (2) do not contest personal jurisdiction in this District, and (3) purposefully avail themselves of the rights and benefits of this Court by asserting claims and/or counterclaims in this District. *See, e.g.*, *Teva Branded Pharmaceutical Products R&D, Inc. & Norton (Waterford) Ltd. v. Cipla Ltd.*, Civil Action No. 20-14890 (JXN)(MAH) (D.N.J.); *Par Pharmaceutical, Inc., et al v. Cipla Ltd. & Cipla USA, Inc.*, Civil Action No. 23-1150 (MCA)(JBC) (D.N.J.); *Fennec Pharmaceuticals, Inc., et al v. Cipla Ltd. & Cipla USA, Inc.*, Civil Action No. 23-123 (JKS)(MAH) (D.N.J.); *Celgene Corp. v. Cipla Ltd.*, Civil Action No. 19-14731 (SDW)(LDW) (D.N.J.); *Cubist Pharm. LLC v. Cipla USA, Inc. & Cipla Ltd.*, Civil Action No. 19-12920 (BRM)(ZNQ) (D.N.J.).

ANSWER: Paragraph 20 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla does not contest personal jurisdiction over Cipla Limited and Cipla USA, Inc. in this Court for the limited purpose of this litigation. Cipla denies the remaining allegations of paragraph 20.

21. For the above reasons, it would not be unfair or unreasonable for Cipla USA, Inc. and/or Cipla Ltd. to litigate this action in this District, and the Court has personal jurisdiction over them here.

ANSWER: Paragraph 21 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla does not contest personal jurisdiction over Cipla Limited and Cipla USA, Inc. in this Court for the limited purpose of this litigation, and denies the remaining allegations of paragraph 21.

VENUE

22. Plaintiffs incorporate each of the proceeding paragraphs 1–21 as if fully set forth herein.

ANSWER: In response to paragraph 22, Cipla repeats and realleges its responses to the allegations of paragraphs 1–21 of the Complaint as if fully set forth herein.

23. Venue is proper in this district for Cipla USA, Inc. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia,* Cipla USA, Inc. is a company with a principal place of business in New Jersey and is subject to personal jurisdiction in this judicial district.

ANSWER: Paragraph 23 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla does not contest venue over Cipla USA, Inc. in this Court for the limited purposes of this litigation. Cipla admits that Cipla USA, Inc. is a company organized and existing under the laws of the State of Delaware, with its principal place of business at 10 Independence Boulevard, Suite 300, Warren, New Jersey 07059. Cipla denies the remaining allegations of paragraph 23.

24. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400(b) with respect to Cipla Ltd., at least because, on information and belief, Cipla Ltd. is a corporation organized and existing under the laws of the Republic of India and is subject to personal jurisdiction in this judicial district.

ANSWER: Paragraph 24 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla does not contest venue over Cipla Limited in this Court for the limited purposes of this litigation. Cipla admits that Cipla Limited is a company organized and existing under the laws of India. Cipla denies the remaining allegations of paragraph 24.

BACKGROUND

25. Teva is the holder of New Drug Application ("NDA") No. 207921 for Qvar RediHaler® 40 mcg (beclomethasone dipropionate, 40 mcg) Inhalation Aerosol. Teva's Qvar RediHaler® inhaler is approved by FDA for maintenance treatment of asthma as prophylactic therapy in adults and pediatric patients 4 years of age and older.

ANSWER: Cipla admits that New Drug Application ("NDA") No. 207921 is approved by FDA. Cipla admits that according to the prescribing information for QVAR REDIHALER™, QVAR REDIHALER is a corticosteroid indicated for: "[m]aintenance treatment of asthma as prophylactic therapy in patients 4 years of age and older." Cipla states that the FDA's electronic *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") lists Norton Waterford Ltd. as the holder of NDA 207921. Cipla lacks sufficient information or knowledge to admit or deny the remaining allegations in paragraph 25 and therefore denies them.

The '832 Patent

26. The '832 patent, entitled "Breath Actuated Inhaler" (Exhibit A), duly and legally issued on April 16, 2024.

ANSWER: Cipla admits that Exhibit A to the Complaint purports to be a copy of the '832 patent. Cipla admits that the '832 patent is titled "Breath Actuated Inhaler" and lists April 16, 2024 as the issue date. Cipla denies the remaining allegations of paragraph 26.

27. Norton is the owner and assignee of the '832 patent.

ANSWER: According to the U.S. Patent and Trademark Office assignment database, Norton (Waterford) Limited is listed as the assignee of the '832 patent. Cipla lacks sufficient information or knowledge to admit or deny the remaining allegations in paragraph 27 and therefore denies them.

28. The '832 patent is listed in connection with the Qvar RediHaler® in the Orange Book.

ANSWER: Cipla admits that the FDA's Orange Book associates the '832 patent with NDA 207921. Cipla denies any remaining allegations of paragraph 28.

29. Claim 1 of the '832 patent claims:

A valve port for a pneumatic force holding unit in a breath actuated metered dose inhaler, said valve port comprising:

a valve seal surface configured to be sealably engaged by a movable valve seal, wherein the valve seal surface has a surface roughness average (RA) of less than about 0.15 μm; and

an annular boss with an inner wall defining a valve orifice channel wherein;

a volume of the valve orifice channel is greater than about 12.7% of a volume of the annular boss; or

the inner wall defines a frustum of an imaginary cone with an apex angle of greater than about 20 degrees.

ANSWER: Cipla admits that paragraph 29 purports to recite claim 1 of the '832 patent. Cipla denies any remaining allegations of paragraph 29.

ALLEGED INFRINGEMENT BY CIPLA

30. On information and belief, Cipla submitted ANDA No. 219000 to FDA under 21 U.S.C. § 355(j), in order to obtain approval to engage in the commercial manufacture, use or sale in the United States of Cipla's ANDA Product.

ANSWER: Cipla admits that Cipla Limited prepared and submitted Cipla's ANDA to the FDA pursuant to 21 U.S.C. § 355(j), and that Cipla's ANDA seeks approval from the FDA to engage in the commercial manufacture, use, and/or sale of Cipla's ANDA Product. Cipla denies the remaining allegations in paragraph 30.

31. On information and belief, Cipla will manufacture, offer for sale, or sell Cipla's ANDA Products within the United States, including within New Jersey, or will import Cipla's ANDA Products into the United States, including New Jersey.

ANSWER: Cipla denies the allegations of Paragraph 31 as phrased, and affirmatively states that it will decide whether to market its product in the United States upon FDA approval.

32. On information and belief, Defendants will actively induce or contribute to infringement by Cipla's ANDA Product.

ANSWER: Denied.

33. By letter dated January 4, 2024 ("Cipla's First Notice Letter"), Cipla notified Teva that it was seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product.

ANSWER: Cipla admits by a letter dated January 4, 2024, Cipla notified Plaintiffs that it was seeking approval from FDA to engage in the commercial manufacture, use, and/or sale, of Cipla's ANDA product before the expiration of the patents recited in the letter. Cipla denies the remaining allegations of paragraph 33.

34. In Cipla's First Notice Letter, Cipla alleged that U.S. Patent Nos. 8,132,712 (the "'712 patent"), 8,931,476 (the "'476 patent"), 10,022,509 (the "'509 patent"), 10,022,510 (the "'510 patent"), 10,086,156 (the "'156 patent"), 10,561,808 (the "'808 patent"), 10,695,512 (the "'512 patent"), 10,792,447 (the "'447 patent"), 11,395,888 (the "'888 patent"), 11,395,889 (the "'889 patent"), 11,559,637 (the "'637 patent"), and 11,583,643 (the "'643 patent") are invalid, not infringed by the commercial manufacture, use, or sale of Cipla's ANDA Product, and/or unenforceable.

ANSWER: Cipla admits that Cipla's First Notice Letter stated, "Cipla alleges, and has certified to the FDA, that in its opinion and to the best of its knowledge, each claim of the RediHaler Patents is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, importation, offer for sale, or sale of the drug product described in Cipla's ANDA." Further, Cipla admits that Cipla's First Notice Letter stated, "the patents subject to the paragraph IV certification alleged to be invalid, and/or not infringed, and/or unenforceable, are U.S. Patent Nos. 8,132,712, 8,931,476, 10,022,509, 10,022,510, 10,086,156, 10,561,808, 10,695,512, 10,792,447, 11,395,888, 11,395,889, 11,559,637, and 11,583,643." Cipla denies the remaining allegations of paragraph 34.

35. In Cipla's First Notice Letter, Cipla stated that the subject of Cipla's ANDA is "Beclomethasone Dipropionate HFA Inhalation Aerosol, 40 mcg."

ANSWER: Cipla admits that Cipla's First Notice Letter stated that "the subject of Cipla's ANDA is Beclomethasone Dipropionate HFA Inhalation Aerosol, 40 mcg." Cipla denies the remaining allegations of paragraph 35.

36. In Cipla's First Notice Letter, Cipla stated that the active ingredient of Cipla's ANDA Product is beclomethasone dipropionate.

ANSWER: Cipla admits that Cipla's First Notice Letter states that the "active ingredient of Cipla's proposed drug product is beclomethasone dipropionate." Cipla denies the remaining allegations of paragraph 36.

37. In Cipla's First Notice Letter, Cipla stated that the proposed dosage strength of Cipla's ANDA Product is 40 mcg per actuation.

ANSWER: Cipla admits that Cipla's First Notice Letter stated, "[t]he dosage form of the proposed drug product is 40 mcg per actuation." Cipla denies the remaining allegations of paragraph 37.

38. In Cipla's First Notice Letter, Cipla stated that the established name of the proposed drug product that is the subject of Cipla's ANDA is "Beclomethasone Dipropionate HFA Inhalation Aerosol, 40 mcg."

ANSWER: Cipla admits that Cipla's First Notice Letter states that the "established name of the proposed drug product that is the subject of Cipla's ANDA is Beclomethasone Dipropionate HFA Inhalation Aerosol, 40 mcg." Cipla denies the remaining allegations of paragraph 38.

39. Cipla's First Notice Letter purported to provide Teva with an Offer of Confidential Access ("OCA") to portions of Cipla's ANDA ("Cipla's First OCA"). That offer, however, was subject to various unreasonably restrictive conditions.

ANSWER: Cipla admits that it provided an Offer of Confidential Access ("OCA") to Cipla's ANDA with its First Notice Letter ("Cipla's First OCA"). Cipla denies the remaining allegations of paragraph 39.

40. In an exchange of correspondence, counsel for Plaintiffs and counsel for Cipla discussed the terms of Cipla's First OCA. The parties did not agree on terms under which Plaintiffs could review, among other things, Cipla's ANDA and any Drug Master File referred to therein, and Cipla refused to produce samples of Cipla's ANDA Product and other internal documents and material relevant to infringement.

ANSWER: Cipla admits that counsel for Plaintiffs and Cipla communicated regarding Cipla's First OCA. Cipla denies the remaining allegations of paragraph 40.

41. On January 16, 2024, Teva's counsel sent Cipla's counsel a letter requesting documents and identifying various unreasonably restrictive terms in Cipla's First OCA, including but not limited to restrictions on the conduct of Teva's outside counsel in future post-grant and FDA proceedings, prohibitions on providing information to outside consultants, choice of law, and limitations on the scope of documents Cipla would provide to Teva.

ANSWER: Cipla admits that Teva's counsel sent Cipla's counsel a letter on January 16, 2024. Cipla denies the remaining allegations of paragraph 41.

42. On January 25, 2024, Cipla's counsel sent Teva's counsel an email refusing to provide the documents and materials requested by Teva and necessary to evaluate Cipla's ANDA Products for infringement.

ANSWER: Cipla admits that counsel for Cipla sent Teva's counsel an email on January 25, 2024. Cipla denies the remaining allegations of paragraph 42.

43. On February 8, 2024, Teva's counsel reiterated to Cipla's counsel via email Teva's need for specific materials to evaluate infringement and proposed reasonable terms for confidentiality protections.

ANSWER: Cipla admits that counsel for Teva sent Cipla's counsel an email on February 8, 2024. Cipla denies the remaining allegations of paragraph 43.

44. Teva's counsel did not receive a response to its February 8, 2024 email.

ANSWER: Cipla admits that the complaint resulting from Cipla's First Notice Letter (Civil Action No. 2:24-cv-00909-SRC-MAH) was filed before Cipla's counsel had an opportunity to respond to the February 8, 2024 email from Teva's counsel.

45. On February 16, 2024, Teva sued Cipla for infringement of the patents identified in Cipla's First Notice Letter in this district. *See* Civil Action No. 2:24-cv-00909-SRC-MAH.

ANSWER: Admitted.

46. By letter dated March 15, 2024 ("Cipla's Second Notice Letter"), Cipla notified Teva that it had filed Paragraph IV Certifications with respect to the '953 patent and the '247 patent and was seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product prior to the expiration of the '953 patent and the '247 patent. On information and belief, Cipla's ANDA contains Paragraph IV Certifications asserting that the '953 patent and the '247 patent will not be infringed by the manufacture, use, offer for sale, sale, or importation of Cipla's ANDA Product, or alternatively, that the '953 patent and the '247 patent are invalid.

ANSWER: Cipla admits by a letter dated March 15, 2024 ("Cipla's Second Notice Letter"), Cipla notified Plaintiffs that it was seeking approval from FDA to engage in the commercial manufacture, use, and/or sale, of Cipla's ANDA product before the expiration of the '953 patent and the '247 patent. Cipla further admits that Cipla's Second Notice Letter notified Plaintiffs that Cipla's ANDA includes a paragraph IV certification that the '953 patent and the '247 patent are alleged to be invalid, and/or not infringed, and/or unenforceable. Cipla denies the remaining allegations of paragraph 46.

47. Cipla's Second Notice Letter purported to provide Teva with a second OCA to portions of Cipla's ANDA ("Cipla's Second OCA"). That offer, however, was subject to the same unreasonably restrictive conditions as Cipla's First OCA.

ANSWER: Cipla admits that it provided an offer of confidential access to Cipla's ANDA with its Second Notice Letter ("Cipla's Second OCA"). Cipla denies the remaining allegations of paragraph 47.

48. In an exchange of correspondence, counsel for Plaintiffs and counsel for Cipla discussed the terms of Cipla's Second OCA. Counsel for Plaintiffs and counsel for Cipla agreed that the impasse regarding Cipla's First OCA remained with respect to Cipla's Second OCA.

ANSWER: Cipla admits that counsel for Plaintiffs and Cipla communicated regarding Cipla's Second OCA. Cipla denies the remaining allegations of paragraph 48.

49. By letter dated April 23, 2024 ("Cipla's Third Notice Letter"), Cipla notified Teva that it had filed a Paragraph IV Certification with respect to the '759 patent and was seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product prior to the expiration of the '759 patent and the '759 patent. On information and belief, Cipla's ANDA contains a Paragraph IV Certification asserting that the '759 patent will not be infringed by the manufacture, use, offer for sale, sale, or importation of Cipla's ANDA Product, or alternatively, that the '759 patent is invalid.

ANSWER: Cipla admits by a letter dated April 23, 2024 ("Cipla's Third Notice Letter"), Cipla notified Plaintiffs that it was seeking approval from FDA to engage in the commercial manufacture, use, and/or sale, of Cipla's ANDA product before the expiration of the '759 patent. Cipla further admits that Cipla's Third Notice Letter notified Plaintiffs that Cipla's ANDA includes a paragraph IV certification that the '759 patent is alleged to be invalid, and/or not infringed, and/or unenforceable. Cipla denies the remaining allegations of paragraph 49.

50. Cipla's Third Notice Letter purported to provide Teva with a third OCA to portions of Cipla's ANDA ("Cipla's Third OCA"). That offer, however, was subject to the same unreasonably restrictive conditions as Cipla's First OCA and Cipla's Second OCA.

ANSWER: Cipla admits that it provided an offer of confidential access to Cipla's ANDA with its Third Notice Letter ("Cipla's Third OCA"). Cipla denies the remaining allegations of paragraph 50.

51. On May 6, 2024, Teva sued Cipla for infringement of the patents identified in Cipla's Second Notice Letter and Cipla's Third Notice Letter in this district. *See* Civil Action No. 2:24-cv-05856-SRC-MAH.

ANSWER: Admitted.

52. By letter dated May 31, 2024 ("Cipla's Fourth Notice Letter"), Cipla notified Teva that it had filed a Paragraph IV Certification with respect to the '832 patent and was seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product prior to the expiration of the '832 patent and the '832 patent. On information and belief, Cipla's ANDA contains a Paragraph IV Certification asserting that the '832 patent will not be infringed by the manufacture, use, offer for sale, sale, or importation of Cipla's ANDA Product, or alternatively, that the '832 patent is invalid.

ANSWER: Cipla admits by a letter dated May 31, 2024 ("Cipla's Fourth Notice Letter"), Cipla notified Plaintiffs that it was seeking approval from FDA to engage in the commercial manufacture, use, and/or sale, of Cipla's ANDA product before the expiration of the '832 patent. Cipla further admits that Cipla's Fourth Notice Letter notified Plaintiffs that Cipla's ANDA includes a paragraph IV certification that the '832 patent is alleged to be invalid, and/or not infringed, and/or unenforceable. Cipla denies the remaining allegations of paragraph 52.

53. The purpose of Cipla's submission of Cipla's ANDA was to obtain approval under the Federal Food, Drug and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product prior to the expiration of the '832 patent.

ANSWER: Cipla admits that it submitted an ANDA seeking approval from the FDA to engage in the commercial manufacture, use, and/or sale of Cipla's ANDA Product prior to the expiration of the '832 patent. Cipla denies the remaining allegations of paragraph 53.

54. Cipla's Fourth Notice Letter purported to provide Teva with a fourth OCA to portions of Cipla's ANDA ("Cipla's Fourth OCA"). That offer, however, was subject to the same unreasonably restrictive conditions as Cipla's First OCA, Cipla's Second OCA, and Cipla's Third OCA.

ANSWER: Cipla admits that it provided an offer of confidential access to Cipla's ANDA with its Fourth Notice Letter ("Cipla's Fourth OCA"). Cipla denies the remaining allegations of paragraph 54.

55. In an exchange of correspondence, counsel for Plaintiffs and counsel for Cipla discussed the terms of Cipla's Fourth OCA. Counsel for Plaintiffs and counsel for Cipla agreed that the impasse regarding Cipla's First OCA, Cipla's Second OCA, and Cipla's Third OCA remained with respect to Cipla's Fourth OCA.

ANSWER: Cipla admits that counsel for Plaintiffs and Cipla communicated regarding Cipla's Fourth OCA. Cipla denies the remaining allegations of paragraph 55.

56. Cipla's Fourth Notice Letter appends a document titled "Detailed Factual and Legal Basis for Cipla's Paragraph IV Certification Regarding U.S. Patent No. 11,957,832" ("Cipla's Fourth Detailed Statement") asserting that the '832 patent is invalid. However, Cipla's Fourth

Detailed Statement fails to demonstrate that the '832 patent is invalid. Further, Cipla's Fourth Detailed Statement does not provide any information regarding Cipla's ANDA Product.

ANSWER: Cipla admits that Cipla's Fourth Notice Letter included a "Detailed Factual and Legal Basis for Cipla's Paragraph IV Certification" that the '832 patent is invalid, unenforceable, and/or will not be infringed. Cipla denies the remaining allegations of paragraph 56.

57. The Court has ordered that this action shall be consolidated with Civil Action No. 2:24-cv-00909-SRC-MAH and Civil Action No. 2:24-cv-05856-SRC-MAH and that Cipla's answers in the consolidated case shall be due by July 3, 2024. Civil Action No. 24-909, D.I. 13; Civil Action No. 24-5856, D.I. 10.

ANSWER: Admitted.

COUNT 1 – ALLEGED INFRINGEMENT BY CIPLA OF THE '832 PATENT UNDER 35 U.S.C. § 271(e)(2)

58. Plaintiffs incorporate each of the preceding paragraphs 1–57 as if fully set forth herein.

ANSWER: In response to paragraph 58, Cipla repeats and realleges its responses to the allegations of paragraphs 1–57 of the Complaint as if fully set forth herein.

59. Cipla's submission of Cipla's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product prior to the expiration of the '832 patent was an act of infringement of the '832 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

60. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe at least claim 1 of the '832 patent, recited above, either literally or under the doctrine of equivalents.

ANSWER: Denied.

61. On information and belief, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product immediately and imminently upon FDA approval of Cipla's ANDA.

ANSWER: Denied.

62. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe at least claim 1 of the '832 patent, recited above.

ANSWER: Denied.

63. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '832 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Denied.

64. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling is especially made or adapted for use in infringing the '832 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '832 patent after approval of Cipla's ANDA.

ANSWER: Denied.

65. The foregoing actions by Cipla constitute and/or will constitute infringement of the '832 patent, active inducement of infringement of the '832 patent, and contribution to the infringement by others of the '832 patent.

ANSWER: Denied.

66. On information and belief, Cipla has acted with full knowledge of the '832 patent and without a reasonable basis for believing that it would not be liable for infringing the '832 patent, actively inducing infringement of the '832 patent, and contributing to the infringement by others of the '832 patent.

ANSWER: Denied.

67. Unless Cipla is enjoined from infringing the '832 patent, actively inducing infringement of the '832 patent, and contributing to the infringement by others of the '832 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 67 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of paragraph 67.

COUNT 2 – DECLARATORY JUDGMENT OF ALLEGED INFRINGEMENT BY CIPLA OF THE '832 PATENT

68. Plaintiffs incorporate each of the preceding paragraphs 1–67 as if fully set forth herein.

ANSWER: In response to paragraph 68, Cipla repeats and realleges its responses to the allegations of paragraphs 1–67 of the Complaint as if fully set forth herein.

69. Cipla has knowledge of the '832 patent as evidenced, for example, by their knowledge of the Orange Book and submission of the Notice Letter.

ANSWER: Cipla's Notice Letter speaks for itself. Cipla denies the remaining allegations of paragraph 69.

70. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe of at least claim 1 of the '832 patent, recited above, either literally or under the doctrine of equivalents.

ANSWER: Denied.

71. On information and belief, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product with its proposed labeling upon FDA approval of Cipla's ANDA.

ANSWER: Denied.

72. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe at least claim 1 of the '832 patent, recited above.

ANSWER: Denied.

73. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '832 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Denied.

74. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '832 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '832 patent after approval of Cipla's ANDA.

ANSWER: Denied.

75. The foregoing actions by Cipla constitute and/or will constitute infringement of the '832 patent, active inducement of infringement of the '832 patent, and contribution to the infringement by others of the '832 patent.

ANSWER: Denied.

76. On information and belief, Cipla has acted without a reasonable basis for believing that it would not be liable for infringing the '832 patent, actively inducing infringement of the '832 patent, and contributing to the infringement by others of the '832 patent.

ANSWER: Denied.

77. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Cipla regarding whether Cipla's manufacture, use, sale, offer for sale, or importation into the United States of Cipla's ANDA Product with its proposed labeling according to Cipla's ANDA will infringe at least claim 1 of the '832 patent, recited above, and whether said claim or claims of the '832 patent are valid.

ANSWER: Paragraph 77 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla admits that an actual case or controversy exists between Plaintiffs and Cipla with respect to the alleged infringement of the '832 patent and the invalidity of the '832 patent. Cipla denies the remaining allegations of paragraph 77.

78. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Cipla's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '832 patent and that the claims of the '832 patent are valid.

ANSWER: Paragraph 78 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of paragraph 78.

79. Cipla should be enjoined from infringing the '832 patent, actively inducing infringement of the '832 patent, and contributing to the infringement by others of the '832 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 79 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of paragraph 79.

TEVA'S REQUEST FOR RELIEF

The remainder of the Complaint is a prayer for relief and does not require a response. To the extent any response is required Cipla denies that Plaintiffs are entitled to any remedy or relief sought in paragraphs (a) through (j) on pages 16 through 17 of the Complaint. Should Teva receive any of their requested relief, no such relief should prevent Cipla from obtaining a Pre-Launch Activities Importation Request from the FDA, or acting under it, in connection with Cipla's ANDA Product. All other allegations in the Complaint not specifically admitted or denied are hereby denied.

SEPARATE DEFENSES

Without prejudice to the denials set forth in its responses to paragraphs 1 through 79 of the Complaint, Cipla alleges the following Separate Defenses to the Complaint. Cipla expressly reserves the right to allege additional defenses as they become known through the course of discovery or other factual investigation. Cipla does not intend to hereby assume the burden of proof with respect to those matters as to which, pursuant to law, Plaintiffs bear the burden of proof.

First Defense
(Invalidity and Ineligibility of the '832 Patent)

Each claim of the '832 patent is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

Second Defense
(Noninfringement of the '832 Patent)

Cipla has not, does not, and will not infringe any valid and enforceable claim of the '832 patent. The manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product has not, does not, and will not infringe, directly or indirectly, any valid and enforceable claim of the '832 patent, either literally or under the doctrine of equivalents.

Third Defense
(Waiver)

Plaintiffs have waived any defect in the manner in which Cipla served Cipla's Fourth Notice Letter and/or are estopped from contesting any alleged defect in service of Cipla's Notice Letter.

Fourth Defense
(Estoppel)

Plaintiffs are estopped from asserting infringement by the doctrine of prosecution history estoppel, equitable estoppel, unclean hands, waiver, implied waiver, acquiescence, disclaimer, judicial estoppel, and/or other equitable doctrines.

Fifth Defense
(Failure to State a Claim)

Plaintiffs' Complaint fails to state a claim upon which relief may be granted.

Sixth Defense
(No Exceptional Case)

Cipla's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

Seventh Defense
(No Willful Infringement)

Cipla has not willfully infringed any claim of the '832 patent.

Eighth Defense
(Ensnarement)

To the extent Plaintiffs claim infringement of one or more claims of the '832 patent under the doctrine of equivalents, Plaintiffs' claims are barred under the ensnarement doctrine, which prohibits Plaintiffs from asserting an infringement theory under the doctrine of equivalents that encompasses or ensnares the prior art.

Ninth Defense
(Lack of Standing)

To the extent that Plaintiffs did not, or do not, hold all substantial rights, title, and interest to the ’832 patent, Plaintiffs lacks standing to bring, or maintain, this lawsuit in connection with such patent.

Tenth Defense
(Reservation of Defenses)

Defendants reserve all affirmative defenses under Rule 8(c) of the Federal Rules of Civil Procedure, the patent laws of the United States, and any other defenses at law or in equity that may exist now or that may be available in the future, including, but not limited to, those related to the unenforceability of any claim of the ’832 patent based on inequitable conduct, as may be determined through discovery and further factual investigation in this actions.

COUNTERCLAIMS

Without admitting the allegations of Plaintiffs Teva Branded Pharmaceutical Products, Inc. (“Teva”) and Norton (Waterford) Ltd. (“Norton”) (collectively, “Plaintiffs” or “Counterclaim Defendants”), other than those expressly admitted herein, Defendants Cipla USA, Inc. and Cipla Limited (collectively, “Cipla” or “Defendants” or “Counterclaim Plaintiffs”) bring the following Counterclaims against Plaintiffs/Counterclaim Defendants for declaratory judgment that U.S. Patent No. 11,957,832 (the “’832 patent”) is invalid and/or not infringed by Cipla and the product as described in Cipla’s Abbreviated New Drug Application (“ANDA”) No. 219000 (“Cipla’s ANDA Product”):

The Parties

1. Counterclaim Plaintiff Cipla Limited is an entity organized and existing under the laws of India, having a place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai 400013, India.

2. Counterclaim Plaintiff Cipla USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 10 Independence Boulevard, Suite 300, Warren, NJ 07059.

3. Upon information and belief, based on the allegations in the Complaint, Counterclaim Defendant Teva Branded Pharmaceutical Products R&D, Inc. ("Teva") is a company organized under the laws of the State of Delaware with its principal place of business at 145 Brandywine Parkway, West Chester, Pennsylvania 19380. In addition, upon information and belief and based on the allegations in the Complaint, Teva has a place of business at 400 Interpace Parkway #3, Parsippany, New Jersey 07054.

4. Upon information and belief, based on the allegations in the Complaint, Counterclaim Defendant Norton (Waterford) Ltd. ("Norton") is a private limited company organized under the laws of the Republic of Ireland and having its registered office at Unit 301, IDA Industrial Park, Waterford X91 WK68, Republic of Ireland.

5. Upon information and belief, based on the allegations in the Complaint, Counterclaim Defendant Norton trades, i.e., does business, as Ivax Pharmaceuticals Ireland and as Teva Pharmaceuticals Ireland.

6. Upon information and belief, and based on the FDA's Orange Book, Counterclaim Defendant Norton is the holder of New Drug Application ("NDA") No. 207921. Based on the allegations in the complaint, Counterclaim Defendant Teva is the holder of New Drug Application ("NDA") No. 207921.

7. Upon information and belief, Counterclaim Defendants currently promote and market Qvar RediHaler® in the United States.

Jurisdiction and Venue

8. This court has subject matter jurisdiction over the Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 2201, 2202, 1331, 1338(a), and 1367, based on an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants arising under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*

9. This Court has personal jurisdiction over Counterclaim Defendants because Counterclaim Defendants have availed themselves of the rights and privileges and subjected themselves to the jurisdiction of this forum by suing Cipla in this judicial district.

10. Venue is proper in this district for the purposes of these Counterclaims because Counterclaim Defendants filed the present action in this district.

11. On or about June 21, 2024, Counterclaim Defendants filed a civil action in this judicial district against Cipla alleging infringement of the ’832 patent. There is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding Cipla and Cipla’s ANDA Product’s non-infringement and validity of the ’832 patent.

The ’832 patent

12. Based on the allegations in the Complaint, the ’832 patent, entitled “Breath Actuated Inhaler,” was issued on April 16, 2024. The face of the ’832 patent lists Norton (Waterford) Limited as the assignee. According to the U.S. Patent and Trademark Office assignment database, Norton (Waterford) Limited is listed as the assignee of the ’832 patent.

13. The ’832 patent is listed in the electronic version of the *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* (“the Orange Book”) in association with QVAR REDIHALER®.

14. On May 31, 2024, pursuant to 21 U.S.C. §355(j)(2)(B)(ii) and 21 C.F.R. § 319.95, Cipla sent Plaintiffs notification of Paragraph IV Certification for the ’832 patent with respect to Cipla’s Abbreviated New Drug Application (“ANDA”) No. 219000 (“Cipla’s ANDA”), which seeks approval from the FDA to engage in the commercial manufacture, distribution, use, offer for sale, sale, and/or import of the product described in Cipla’s ANDA (“Cipla’s ANDA Product”) (“Cipla’s Fourth Notice Letter”).

15. In accordance with 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Cipla’s Fourth Notice Letter included, among other things, Cipla’s detailed factual and legal basis for the paragraph IV certification regarding the ’832 patent as it pertains to Cipla’s ANDA Product and an offer of confidential access (“Cipla’s Fourth OCA”).

16. On or about June 21, 2024, Counterclaim Defendants brought this present action alleging infringement of the ’832 patent.

First Counterclaim
(Declaratory Judgment of Noninfringement of the ’832 Patent)

17. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 16 of the Counterclaims as if fully set forth herein.

18. Counterclaim Defendants have accused Cipla of infringing the ’832 patent.

19. Cipla denies infringement of the ’832 patent and alleges that the manufacture, use, sale, offer for sale, and/or importation of Cipla’s ANDA Product does not, and would not, if

marketed, infringe, induce infringement of or contribute to infringement of, either literally or under the doctrine of equivalents, any valid and enforceable claims of the ’832 patent.

20. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding infringement of any valid and enforceable claim of the ’832 patent.

21. Cipla is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Cipla’s ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the ’832 patent.

Second Counterclaim
(Declaratory Judgment of Invalidity of the ’832 Patent)

22. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 21 of the Counterclaims as if fully set forth herein.

23. The claims of the ’832 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

24. For at least the reasons stated in Cipla’s Fourth Notice Letter, which is hereby incorporated by reference in its entirety, the claims of the ’832 patent are not infringed by Cipla’s ANDA Product and/or are invalid.

25. Upon information and belief, Cipla believes that Counterclaim Defendants will continue to assert that Cipla’s ANDA Product is infringing the claims of the ’832 patent and will continue to try to interfere with Cipla’s business with respect to Cipla’s ANDA Product.

26. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of all claims of the '832 patent.

27. Cipla is entitled to a judicial declaration that all claims of the '832 patent are invalid for failure to satisfy one or more of the requirements of Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

Request for Relief

WHEREFORE, Cipla requests that this Court enter judgment against Counterclaim Defendants:

A. Declaring that the manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product does not and will not directly or indirectly infringe any claim of the '832 patent, either literally or under the doctrine of equivalents;

B. Declaring that the claims of the '832 patent are invalid and/or unenforceable;

C. Ordering that Counterclaim Defendants' Complaint be dismissed with prejudice and judgment entered in favor of Cipla;

D. Preliminarily and permanently enjoining Counterclaim Defendants, its employees and agents, and any other person acting in concert with any of them, from asserting or threatening to assert any alleged rights arising under the '832 patent against Cipla or any person or entity working in concert with Cipla;

E. Awarding Cipla its costs and expenses incurred in this action;

F. Declaring that this is an exceptional case in favor of Cipla and awarding Cipla its reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

G. Awarding Cipla such other and further relief as the Court may deem proper.

DATED: July 3, 2024

Respectfully submitted,

K&L GATES LLP

By: /s/ *Loly G. Tor*

Loly Tor (loly.tor@klgates.com)
K&L GATES LLP
One Newark Center, 10th Floor
Newark, NJ 07102
(T) 973.848.4026
(F) 973.848.4001

Of Counsel:

Anil H. Patel (anil.patel@klgates.com)
(*pro hac vice* application forthcoming)
K&L GATES LLP
609 Main Street, Suite 4150
Houston, TX 77002
(T) 713.815.7300
(F) 713.815.7301

Harold Storey (harold.storey@klgates.com)
(*pro hac vice* application forthcoming)
Elizabeth Weiskopf
(elizabeth.weiskopf@klgates.com)
(*pro hac vice* application forthcoming)
K&L GATES LLP
925 Fourth Avenue, Suite 2900
Seattle, WA 98104
(T) 206.623.7580
(F) 206.623.7022

Attorneys for Defendants/Counterclaim-Plaintiffs
Cipla Limited and Cipla USA, Inc.

LOCAL CIVIL RULE 11.2 CERTIFICATION

Under Local Civil Rule 11.2, the undersigned counsel for Cipla Limited and Cipla USA, Inc. hereby certifies that, the following actions involve patents related to the '832 patent asserted in the instant action:

- *Teva Branded Pharmaceutical Products R&D, Inc., et al., v. Cipla USA, Inc. and Cipla Ltd.*, No. 2:24-cv-00909-SRC-MAH, pending before the United States District Court for the District of New Jersey, in which Plaintiffs asserted, *inter alia*, patents related to the Patents-in-Suit against Defendants in connection with Defendants' submission of ANDA No. 219000;
- *Teva Branded Pharmaceutical Products R&D, Inc., et al., v. Cipla USA, Inc. and Cipla Ltd.*, No. 2:24-cv-05856-SRC-MAH, pending before the United States District Court for the District of New Jersey, in which Plaintiffs asserted claims of patent infringement against Defendants in connection with Defendants' submission of ANDA No. 219000.

I certify under penalty of perjury that the foregoing is true and correct.

Dated: July 3, 2024

Respectfully submitted,

K&L GATES LLP

By: /s/ *Loly G. Tor*

Loly G. Tor (loly.tor@klgates.com)
One Newark Center, 10th Floor
Newark, NJ 07102
(T) 973.848.4026
(F) 973.848.4001

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Pursuant to Local Civil Rule 201.1, the undersigned counsel for Cipla Limited and Cipla USA, Inc. hereby certifies that this action involves a request for injunctive relief and therefore this action is not appropriate for compulsory arbitration.

Dated: July 3, 2024

Respectfully submitted,

K&L GATES LLP

By: /s/ *Loly G. Tor*

Loly G. Tor (loly.tor@klgates.com)
One Newark Center, 10th Floor
Newark, NJ 07102
(T) 973.848.4026
(F) 973.848.4001

Loly Tor (loly.tor@klgates.com)
K&L GATES LLP
One Newark Center, 10th Floor
Newark, NJ 07102
(T) 973.848.4026
(F) 973.848.4001

Attorneys for Defendants/Counterclaim-Plaintiffs Cipla USA, Inc. and Cipla Limited

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC. and NORTON (WATERFORD) LTD., Plaintiffs, v. CIPLA USA, INC. and CIPLA LTD., Defendants.	Civil Action No. 2:24-cv-07162 Hon. Stanley R. Chesler, U.S.D.J. Hon. Michael A. Hammer, U.S.M.J. **CERTIFICATE OF SERVICE** ***Document Electronically Filed***

LOLY G. TOR, of full age, hereby certifies as follows:

1. I am an attorney-at-law of the State of New Jersey and admitted to practice before the United States District Court for the District of New Jersey and partner with the law firm of K&L Gates LLP, attorneys for Defendants/Counterclaim-Plaintiffs Cipla Limited and Cipla USA, Inc.

2. I hereby certify that on the date indicated below, I caused a copy of Defendants/Counterclaim-Plaintiffs Cipla Limited and Cipla USA, Inc.'s Answer, Separate

Defenses, and Counterclaims, Fed. R. Civ. P. 7.1 Corporate Disclosure Statement, and this certificate of service to be served upon all counsel of record by CM/ECF and e-mail.

3. I certify under penalty of perjury that the foregoing is true and correct.

Dated: July 3, 2024

Respectfully submitted,

K&L GATES LLP

By: /s/ *Loly G. Tor*

Loly G. Tor (loly.tor@klgates.com)
One Newark Center, 10th Floor
Newark, NJ 07102
(T) 973.848.4026
(F) 973.848.4001